

APR 17 2012

**510(k) Summary Of Safety And Effectiveness**

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**Summary Date** April 4, 2012

**Submitter Name and Address** Stryker Neurovascular  
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**Contact Person:** Rhoda Santos  
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**Trade Name:** Target® Detachable Coils

**Common Name:** Occlusion Coil, Vascular Occlusion Coil, Neurovascular Occlusion Coil

**Classification Name:** Target Detachable Coils are classed as vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively, and are Class II devices (special controls).

The special control for the devices is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

## 510(k) Summary Of Safety And Effectiveness (cont.)

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### Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K093142 (4 Feb 2010)	Target Detachable Coil and InZone® Detachment System
K102672 (15 Oct 2010)	Target Detachable Coil
K112385 (15 Sept 2011)	Target Detachable Coil

### Device Description:

Stryker Neurovascular's (Boston Scientific) **Target Detachable Coils** are comprised of four coil types: **Target Coil 360 STANDARD**, **Target Coil 360 SOFT**, **Target Coil 360 ULTRA** and **Target Coil HELICAL ULTRA**. All Target Coils are stretch resistant coils. Target Coils incorporate a length of multi-strand material through the center of the coil designed to help resist stretching. Target Coils are designed for use with Stryker Neurovascular's InZone™ Detachment System (sold separately).

Each Target Coil type consists of a platinum-tungsten alloy coil attached to a stainless steel delivery wire. For Target Coil 360 STANDARD, Target Coil 360 SOFT and Target Coil 360 ULTRA coils the distal end of the main coil is formed such that there is a smaller distal loop at the end of the main coil to facilitate placement of the coil. The diameter of the distal loop is 75% that of the rest of the main coil loops.

The coils are designed to be delivered and deployed under fluoroscopic guidance. Once placement in the anatomy is appropriate, the coil is detached from the delivery wire through the use of the battery-operated power supply. This is accomplished by means of an electrolytic reaction where the anode is the delivery wire and the cathode (or ground) is the return electrode. The body's electrolytes serve as an electrolytic carrier between the two electrodes. The cross section of the stainless steel delivery wire and coil junction is designed in such a manner that when current is applied to the wire, the current causes the exposed stainless steel at the junction to dissolve due to electrolysis, which subsequently disconnects the wire from the coil material. The design of coils allows the electrolytic dissolution to occur only in the detachment zone. Once circuitry in the power supply detects coil detachment, the power supply emits audible beeps signaling detachment and the flow of current is halted. Using fluoroscopy, the physician verifies that the coil has detached and removes the delivery wire without disturbing the newly placed coil. In order to achieve optimum

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occlusion, it is usually necessary to deploy multiple coils at a single embolization site.

The coil properties, namely, the secondary coil shape and stiffness, in concert with each other, impact conformability and optimal packing of the coils in the aneurysm sac. These properties help the coil conform to the contours of the space within which it is deployed. It is important that the coil is able to do this without disrupting the rest of the coil mass. In addition, the coil stretch resistance incorporates an element to help it resist stretching or unraveling under the typical forces exerted upon it during deployment and retraction.

Stryker Neurovascular's (Boston Scientific) InZone Detachment System is intended for use with all Stryker Neurovascular Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

**Verification Testing:** Verification testing of the Target Detachable Coil consisted of the following:

### **Predicate Device Testing (from K102672)**

1) Functional testing to assess:

- Main Junction Tensile Strength
- Delivery Wire Tensile Strength
- Coil Detachment Time

2) MR Compatibility testing to assess:

- Magnetically induced displacement (ASTM F2052)
- Magnetically induced torque (ASTM 2213)
- Magnetically induced heating effect (in 1.5 T and 3 T MR systems - ASTM F2182)
- MR induced image artifact (ASTM F2119)

As a result of MR compatibility testing, the Directions for Use (DFU) for the Target Detachable Coil has been revised to include a more comprehensive MR Conditional statement describing the conditions under which the device was tested.

3) Pre-clinical testing to provide post-implant MR artifact data and to assess and compare the modified Target Detachable Coil to control coils in coiled aneurysm models.

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4) Confirmatory biocompatibility testing as follows:

MEM Elution Cytotoxicity  
Hemolysis, Direct Contact  
USP Physico-Chemical <661>

5) Assessment of the new grade stainless-steel by Boston Scientific's Corporate Toxicology group.

Predicate Device Testing (from K112385)

1) Functional Testing to assess:

- a) Coil / Catheter Compatibility
- b) Product Removal from the Flushing Dispenser Coil (Product Removal Test Method, No Twistlock)

2) Packaging Verification testing to assess the ability of the new introducer sheath to protect the finished device

3) Shelf Life Testing, following climatic conditioning and distribution simulation, to assess the ability of the new introducer sheath to protect the finished device

4) Confirmatory biocompatibility testing as follows:

- a) Cytotoxicity, MEM Elution (EN ISO 10993-5:2009)
- b) Sensitization, Guinea Pig Maximization (EN ISO 10993-10:2009)
- c) Intracutaneous Reactivity (EN ISO 10993-10:2010)
- d) Acute Systemic Injection (EN ISO 10993-11:2009)
- e) Rabbit Pyrogen, Materials Medicated (EN ISO 10993-11:2009)
- f) Hemolysis, Direct Contact ((EN ISO 10993-4:2009)
- g) Partial Thromboplastin Time (EN ISO 10993-4:2009)
- h) In Vitro Hemocompatibility (EN ISO 10993-4:2009)
- i) Complement Activation (EN ISO 10993-4:2009)
- j) USP Physico-Chemical <661>
- k) Latex Testing (ASTM D6499-07)

5) Design Validation testing in which a physician assessed the new introducer sheath and new retention clip for the ability of the new configuration to:

- a) protect the finished device
- b) provide acceptable introducer sheath friction
- c) provide for proper hydration of the finished device within the new introducer sheath
- d) enable easy removal of the finished device from the dispenser coil

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Physician evaluation also assessed whether the revised DFU was clear, legible and easy to read.

### **Testing for modifications that are the subject of this submission**

No new additional testing was conducted for implementation of the new introducer sheath and new retention clip on BSC branded Target coils since the existing testing previously submitted and approved (K112385) covers all Target coil sizes.

### **Accessories:**

Target Detachable Coils are packaged within a flushing dispenser coil assembly. The dispenser coil is an accessory item with an attached flushport used to hydrate the coil prior to use.

### **Indications for Use / Intended Use:**

Target Detachable Coils are intended for use in the treatment of intracranial aneurysms and other neuro and peripheral vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Target Coils are indicated for endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

### **Comparison to Predicate Device:**

#### **Target Detachable Coils**

Stryker Neurovascular's modified Target Detachable Coils have the same intended use/indications for use as the predicate Target Detachable Coils.

Although the devices incorporate modifications to the introducer sheath (i.e., a change in material from polypropylene to high density polyethylene), a new dispenser coil clip, and revised instructions for use, the modifications do not alter the intended use, indications for use, or the fundamental scientific technology of the predicate devices.

Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971 +A1:2003. Stryker Neurovascular has determined the modifications to the predicate devices raise no new questions of safety or effectiveness.

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Verification testing (submitted and approved (K112385)) for the modified Target Detachable Coils are substantially equivalent to the predicate Target Detachable Coils.

**Conclusion:**

Because the subject modifications do not alter the intended use or indications for use of the predicate devices, or the fundamental scientific technology of the predicate devices; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Stryker Neurovascular has determined the modified Target Detachable Coils to be substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Stryker Neurovascular  
c/o Ms. Rhoda Santos  
Regulatory Affairs Project Manager  
47900 Bayside Parkway  
Freemont, CA 94538

APR 17 2012

Re: K120850

Trade/Device Name: Target® Detachable Coils  
Regulation Number: 21 CFR 882.5950  
Regulation Name: Neurovascular Embolization Device  
Regulatory Class: Class II  
Product Code: HCG, KRD  
Dated: March 20, 2012  
Received: March 21, 2012

Dear Ms. Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



**Special 510(k): Modification of Stryker Neurovascular's Target® Detachable Coils**



**INDICATIONS FOR USE STATEMENT**

510(k) Number: K120850

**Device Name:** Target Detachable Coils

**Indications for Use:**

Target Detachable Coils are indicated for the endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over The Counter Use \_\_\_\_\_

Jeffrey Toy  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K120850